

REMARKS

Status of Claims

By this Amendment, claims 1, 4-25, 27-29 and 31-35 are pending. The Examiner has withdrawn claims 7-25, 27, and 28 from consideration as being directed to non-elected inventions. Claims 1, 4-6, 29, and 31-33 are amended herein. New claims 34 and 35 are added.

Support for the amendment to claim 1 and can be found throughout the specification as filed and as presently amended. *See e.g.*, specification at page 2, line 30 - page 3, line 3; page 3, lines 13-21; page 3, lines 24-30; page 4, lines 6-9; page 20, lines 4-17; page 23, lines 1-7; page 6, lines 3-7; page 24, lines 10-14; page 37, lines 16-24; and Table 3.

Support for the amendments to claims 4 and 5 can be found throughout the specification as filed. *See e.g.*, specification at page 8, line 24 - page 9, line 7.

Support for the amendment to claim 6 can be found throughout the specification as filed and as presently amended. *See e.g.*, specification at page 37, lines 16-24; and Table 3.

Support for the amendment to claim 29 can be found throughout the specification as filed and as presently amended. *See e.g.*, specification at page 3, lines 13-21; page 11, lines 16-29; page 37, lines 16-24; and Table 3.

Support for the amendments to claims 31 and 32 can be found throughout the specification as filed. *See e.g.*, specification at page 8, line 24 - page 9, line 7.

Support for the amendment to claim 33 can be found throughout the specification as filed and as presently amended. *See e.g.*, specification at page 3, lines 13-21; page 11, lines 16-29; page 37, lines 16-24; and Table 3.

Support for new claims 34 and 35 can be found throughout the specification as filed, in addition to the support found for their antecedent claims. *See e.g.*, specification at page 9, lines 5-7.

Objections to the Specification

The Examiner objects to the amendment to the specification filed on October 6, 2008, under 35 U.S.C. 132(a), alleging that “it introduces new matter into the disclosure of the invention.” Office Action at 3-4.

The Examiner objects to the changes made to Table 2, wherein, e.g. the recitation of “(4)” was changed to “(0)” for the 6th polypeptide of the table, and wherein the recitation of “(16)” and “(1)” were changed to “(17)” and “(0)”, respectively in the 7th polypeptide of the table. *Id.* at 3. These changes were made to correct typographical errors in the originally filed Table 2. The corrected versions are supported by the sequence data deposited in publicly available databanks which were accessible at the time of the original filing, as indicated by the disclosed SWALL accession numbers. Therefore, these changes do not constitute new matter.

The Examiner points out that SEQ ID NOs: 5-25 filed on December 19, 2007, are not supported by the original SEQ ID NOs: 5-25. Office Action at 4. The Examiner also points out that the SEQ ID NOs: 5-11 “contain many Xaa, which are not supported by the original disclosure.” *Id.* The Examiner states that “[t]he polypeptide identified as SEQ ID NO:30 is now [] SEQ ID NO 21 in the newly filed sequence listing.” *Id.* The Examiner indicates that “appropriate correction is required.” *Id.*

Accordingly, Applicants submit herewith a new substitute sequence listing supported by the sequence data corresponding to the SWALL accession numbers as disclosed in the original

filing. The sequence alignment shown in Table 2 was generated from sequence data deposited in publicly available databanks, which were accessible, at the time of the original filing, using the provided SWALL identifiers on the left column of Table 2. The sequences in Table 2 with a gap or gaps, denoted by “(#)”, are presented as a plurality of separate sequences, with separate sequence identifiers, with the number of separate sequences being equal in number to the number of continuous strings of sequence data. 37 C.F.R. § 1.822(e). Therefore, the new sequence listing is fully supported by the original disclosure and no new matter is added.

As a result of the new sequence listing, the specification has been amended to denote the correct SEQ ID NOs. Furthermore, the paragraph beginning at page 41, line 26 is amended to indicate the SEQ ID NOs for the sequences listed in Table 2. Accordingly, no new matter is added to the specification.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejects claims 1, 4-6, 29, and 31-33 under 35 U.S.C. § 112, second paragraph, as allegedly “being indefinite for failing to particularly point out and distinctively claim the subject matter which applicant regards as the invention.” Office Action at 5.

Applicants respectfully submit that in view of the present amendments, this rejection is moot and should be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejects claims 1, 4-6, 29, and 31-33 under 35 U.S.C. § 112, “first paragraph, new matter,” as allegedly “failing to comply with the written description

requirement.” Office Action at 7. Applicants respectfully submit that in view of the present amendments, this rejection is also moot and should be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejects claims 1, 4-6, 29, and 31-33 under 35 U.S.C. § 112, “first paragraph, written description,” as allegedly “failing to comply with the written description requirement.” Office Action at 8. The Examiner alleges that “[t]he claim(s) contain[] subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time of the application was filed, had possession of the claimed invention.” *Id.* Applicants respectfully submit that in view of the present amendments, this rejection is also moot and should be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejects claims 1, 4-6, 29, and 31-33 under 35 U.S.C. § 112, “first paragraph, scope of enablement,” because the specification allegedly

does not reasonably provide enablement for [a] genus method [that] comprises comparing a structural model of said FIH . . . “for said chemical entity” . . . wherein the FIH structural model is derived from any structural factors or any structural coordinates . . . from Table 3; and does not reasonably provide enablement for [a] genus method comprising using, screening, characterizing or designing any chemical entity that . . . binds to any FIH comprising SEQ ID NO:21, any fragment . . . thereof described by the structural factors or structural coordinates of Table 3; . . . wherein said FIH is [a] very widely varying genus . . . wherein the method step of using, identifying, screening, characterizing, or designing is not limited to any parameter of said steps.

Office Action at 11 and 12. The Examiner further states that “Applicants and prior art disclose no direction or guidance as to how [to] make and use the full scope of the claimed method as

described by the breadth of the claims above.” *Id.* at 13. Applicants respectfully submit that in view of the present amendments, this rejection is also moot and should be withdrawn.

Rejection under 35 U.S.C. § 102

The Examiner rejects claims 1, 3¹, and 5 under 35 U.S.C. § 102 as allegedly “being anticipated by Hewitson et al. (May 31, 2002 E. publication, *The Journal of Biological Chemistry*, vol. 149, pages 26351-26355).” Office Action at 14. Applicants respectfully traverse this rejection.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” M.P.E.P. 2131; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants respectfully submit that Hewitson fails to disclose all of the elements of the instant claims as presently amended. For example, Hewitson fails to disclose any crystal structural model of any polypeptide comprising SEQ ID NO:30. Therefore, this rejection is moot and should be withdrawn.

Rejection under 35 U.S.C. § 103

The Examiner rejects claim 6 under 35 U.S.C. § 103(a) as allegedly “being unpatentable over Hewitson et al. (May 31, 2002 E. publication, *The Journal of Biological Chemistry*, vol. 149, pages 26351-26355).” Office Action at 17. The Examiner also rejects claims “1, 3[sic], 5-6, 29 and 31-32” under 35 U.S.C. § 103(a) as allegedly “being unpatentable over” Hewitson et al. (May 31, *The Journal of Biological Chemistry*, vol. 149, pages 26351-26355) (“Hewitson”)

¹ Claim 3 is cancelled.

and Böhm (J. of Comp.-Aided Mole. Design, 1992, 6:61-78) (“Böhm”) and Goodsell et al. (J. of Molec. Recog., 1996, 9:1-5) (“Goodsell”) in view of *In re Gulack* 217 U.S.P.Q. 401 (Fed. Cir. 1983) and *In re Ngai* 70 U.S.P.Q. 1862 (Fed. Cir. 2004). Office Action at 19. The Examiner alleges that “the method of Hewitson et al anticipates claims 1 and 4-5.” *Id.* at 21. However, the Examiner concedes that “Hewitson et al. do not teach in silico methods for identifying a chemical entity which binds to a FIH polypeptide comprising method step of utilizing the coordinates in table 3.” *Id.* The Examiner concludes that

it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to employ the method as disclosed by Hewitson using any set of structural coordinates as defined in the claims with a reasonable expectation of success by the teachings of Hewitson et al., Böhm and Goodsell et al. in view of Gulak and Ngai.

Id. at 23. Applicants respectfully traverse the rejection.

Determining the obviousness of a claimed invention under 35 U.S.C. § 103 requires the Examiner to apply three factual inquires, which were originally outlined in *Graham v. John Deere Co.*, and reaffirmed in *KSR International Co. v. Teleflex, Inc.* See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 USPQ2d 1385 (2007) (“...the [*Graham*] factors continue to define the inquiry that controls.”). Accordingly, in order to establish a *prima facie* case of obviousness, the Examiner must objectively perform each of the following factual inquiries:

- (A) Ascertain the scope and contents of the prior art;
- (B) Ascertain the differences between the claimed invention and the prior art; and
- (C) Resolve the level of ordinary skill in the pertinent art.

See *Graham* 383 U.S. 1 at 17-18; see also M.P.E.P. § 2141. The obviousness or non-obviousness of the claimed invention is then evaluated in view of the results of these inquiries.

Graham, 383 U.S. at 17-18, 148 U.S.P.Q. at 467; *see also KSR*, 127 S. Ct. at 1734, 82 U.S.P.Q.2d at 1391. Moreover, “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.” M.P.E.P. § 2143 (citing *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)).

As an initial matter, Hewitson teaches a structural model of phosphomannose isomerase, not a structural model of a polypeptide comprising SEQ ID NO:30 or any fragment thereof that retains asparaginyl hydroxylase activity, having a 3-dimensional structure defined by the structural coordinates of structures 1, 2, or 3 in Table 3. Böhm and Goodsell merely teach rational drug design via computer modeling, in general. Thus, the scope and contents of the combination of references cited by the Examiner would not lead a person of ordinary skill to be able to perform the presently claimed methods. Therefore, in view of the instant claims as presently amended, this rejection is moot and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.



By: _____

Mark D. Sweet
Reg. No. 41,469
(202) 408-4000

Dated: April 14, 2009